

### REMARKS

Claims 6-16 are pending in this application. Claims 6-16 have been rejected under 35 U.S.C. §103. Claims 17-28 have been added. The specification has been amended. No new matter has been added. Reexamination and reconsideration are respectfully requested.

The Examiner has rejected Claims 6-10 and 12-16 under 35 U.S.C. §103(a) as being unpatentable over Tune et al., U.S. Patent #5,630,710 in view of Goedeke, U.S. Patent #5,904,708. This rejection is respectfully traversed.

Independent Claim 6 recites a medical system, comprising, *inter alia*, an ambulatory medical device (MD) comprising MD electronic control circuitry that further comprises at least one MD telemetry system and a communication device (CD) comprising CD electronic control circuitry that further comprises at least one CD telemetry system, wherein the CD telemetry system sends messages to or receives messages from the MD telemetry system using RF transmissions. Independent Claim 12 recites similar features. The combination of these features is not suggested in the art cited by the Examiner. Generally, Claims 6-10 and 12-16 recite a medical system having features that are neither described nor suggested by the Tune et al. patent or the Goedeke patent, individually or in combination. For example, as stated in the last-filed reply, the medical system of claims 6-10 includes:

1. a communication device CD that “includes a CD display controlled by the at least one CD processor for providing visual feedback to the patient;” and
2. a communication device CD telemetry system that “sends messages to or receives messages from the MD telemetry system using RF transmissions“

Tune et al. neither describes nor suggests a medical system as claimed, including the above-noted features. The Examiner cites the programmer 952 of the Tune et al. system as corresponding to the “communication device” CD (Office Action, page 3, line 3.) However, the programmer 952 is described by Tune et al. as a “remote programmer” for programming the pump 10 from a remote location relative to the pump and patient.

Because it is designed to be used remotely from the pump and patient, Tune et al.'s "remote programmer" does not include "at least one CD display controlled by the at least one CD processor for providing visual feedback to the patient." While it is contemplated that the remote programmer 952 may be positioned in IR communication with the pump 10 during a programming operation, the display and processor in the remote programmer 952 provide visual feedback to the programming technician, not to the patient. Instead, Tune et al. provide a patient-side display on the pump 10 for providing visual information to the patient (see, e.g., control panel 32 and "patient display 36" on the pump 10). There would be no reason or motivation for the display device in the programmer 952 to provide a visual display to the patient, because the patient already has a visual display in the pump 10. However, the patient-side display in the pump 10 employs the pump processor and, thus, does not employ a separate communication device processor. This distinction was described in greater detail in the response to the first Office Action as a reason why components of the pump 10 would not meet the communication device CD features recited in the claims under rejection.

Similarly, the Goedeke system comprises an external programmer 300 that apparently may include a display (see Fig. 1 of Goedeke), but is used by a physician or other medical personnel during receipt of signal values (Goedeke, column 9, line 62 to column 10, line 1; column 14, lines 2-5). In addition, in the Goedeke system the patient wears a sensor module that may include a wrist watch type display that specifies which timing intervals are employed for the delivery of therapy and for specifying the duration of the various timing intervals. (Goedeke, column 15, lines 36-51). There would be no reason or motivation for the display device in the external programmer 300 of Goedeke to provide a visual display to the patient, because the patient already has a visual display in the wrist watch display 250.

Accordingly, it is respectfully submitted that the Tune et al. and Goedeke patents do not describe nor suggest, individually or in combination, a medical system in which a communication device CD "includes a CD display controlled by the at least one CD processor for providing visual feedback to the patient;" as recited in claims 6-10.

Furthermore, Claims 12-16 recite a medical system also having features that are neither described nor suggested by the Tune et al. and Goedeke patents, individually or in combination. For example, the system of claims 12-16 includes:

1. a CD display that “is controlled to depict a plurality of patient programmable options and wherein at least one of the patient programmable options may be enabled or disabled such that when disabled the at least one patient programmable option is no longer displayed as an option,” and

2. a communication device CD telemetry system that “sends messages to or receives messages from the MD telemetry system using RF transmissions“

As discussed above, because it is designed to be used remotely from the pump and patient, Tune et al.’s “remote programmer” 952 does not include “at least one CD display controlled by the at least one CD processor for providing visual feedback to the patient.” Similarly, Tune et al.’s “remote programmer” 952 does not include a CD display that is controlled to depict a plurality of patient programmable options. The remote programmer 952 is remote from the patient and, thus, would not display patient programmable options, as claimed.

The same argument applies to the Goedeke system. The external programmer 300 does not include “at least one CD display controlled by the at least one CD processor for providing visual feedback to the patient” and does not include a CD display that is controlled to depict a plurality of patient programmable options. The external programmer 300 is remote from the patient and is used by physicians and other medical personell and, thus, would not display patient programmable options, as claimed.

Moreover, Applicant respectfully notes that no motivation has been provided for combining the Tune et al. and Goedeke references. While it has been suggested that it would have been obvious to combine the disclosed invention of Tune et al. with the teachings of Goedeke “because it is well known to use RF telemetry with implantable medical devices, as stated in the entire reference of Goedeke (See Column 1, lines 40 to Column 2, line 6, as well as entire reference),” the Tune et al. system is not an implantable medical device. Rather, Tune et al. describes an external infusion pump, as shown in Figs. 1 and 2 of that patent. Moreover, no

motivation or suggestion has been provided to combine the Tune et al. and Goedeke references, and, consequently, no argument has been given as to why it would have been obvious to employ the RF telemetry of Goedeke's implantable devices with Tune et al.'s external medical devices. Accordingly, without a motivation to combine the Tune et al. and Goedeke references, a *prima facie* case of obviousness has not been made.

The Examiner has also rejected Claim 11 under 35 U.S.C. §103(a) as being unpatentable over Tune et al. with Goedeke and further in view of Er, U.S. Patent #6,185,461. This rejection is respectfully traversed.

Claim 11 is dependent on claim 6. The Er patent does not address the above-noted distinctions between claim 6 and the Tune et al. and Goedeke patents. Accordingly, the rejection of claim 11 is respectfully traversed, at least for the reasons noted above with respect to claim 6.

Applicant has added dependent Claims 17-28. Dependent Claims 17-22 depend either directly or indirectly from Claim 17 while dependent Claims 23-28 depend either directly or indirectly from Claim 12. Claims 17-28 recite further features that are not disclosed or suggested in the Tune et al., Goedeke and Er references, individually or in combination. For example, Claims 17-22 recite that the visual feedback to the patient includes a time-of-day indicator, an alarm icon, a delivery condition, a battery indicator, a reservoir level indicator and an insulin delivery indicator, respectively. These features are not described in the Tune et al., Goedeke and Er references. Claims 17-22 are allowable for at least the same reasons as Claim 6.

Claims 23, 27 and 28 recite that the plurality of patient programmable options include bolus options, a delivery pattern and an alarm option, respectively. Claims 24-26 recite that the bolus options include a normal bolus, a square wave bolus and a dual-phase bolus, respectively. These features are not described in the Tune et al., Goedeke and Er references. Claims 23-28 are allowable for at least the same reasons as Claim 12.

In addition, Applicant has amended the specification to add missing serial numbers and to update docketing numbers.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date 10-29-03

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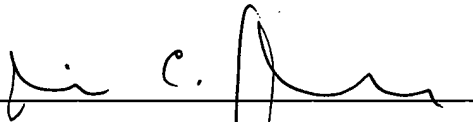


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